

**REMARKS/ARGUMENTS**

Claims 1, 2, 5 and 8-15 are pending in the application. By this Amendment, claims 1 and 8 are amended. Reconsideration and withdrawal of the rejections in view of the foregoing amendments and the following remarks is respectfully requested.

**I. FORMAL MATTERS**

By this Amendment, independent claim 1 is amended to recite that the enteric coating formulation comprises an aqueous solution of shellac salt, and an aqueous solution of alginate, wherein the formulation comprises between 10-90% aqueous solution of shellac salt and between 10-90% aqueous solution of alginate. Claim 8 is amended to agree with the amended version of independent claim 1. These claim amendments are made to clarify the claims, not to distinguish the claims from the prior art.

**II. CLAIM REJECTIONS**

The Office Action rejects claims 1, 2, 5 and 8-15 under 35 USC §103(a) over U.S. Patent No. 5,567,438 to Cook (“Cook”), in view of US Patent No. 6,326,028 to Nivaggioli et al. (“Nivaggioli”), and further in view of US Patent No. 4,778,749 to Vasington et al. (“Vasington”). Because the references would not have motivated one of skill in the art to form an enteric coating as claimed, and because the combination of references is improper, the rejection is respectfully traversed.

The Cook reference discloses that a shellac coating could be applied to various foods, or to pharmaceuticals such as pills and tablets. However, Applicant notes that the Cook patent application was filed in October, 1995.

Subsequent to 1995, the use of shellac as an enteric coating for a pharmaceutical or a nutraceutical became discredited. Over time, those of ordinary skill in the art discovered that a shellac coating does not behave in the manner required of an enteric coating. Instead, shellac behaves more like any erodible coating, dissolving as a function of the time, rather than as a function of pH. As support for these facts, Applicant has enclosed a portion of the *Handbook of Pharmaceutical Excipients*, 3<sup>rd</sup> Edition. Under Section 19 of the enclosed extract, on pages 463 and 464, the Handbook indicates that shellac is not considered a suitable enteric coating.

Because the use of shellac as an enteric coating had been discredited after the publication of the Cook patent, it is respectfully submitted that at the time the present application was filed the Cook patent would not have motivated one of ordinary skill in the art to form an enteric coating using an aqueous solution of shellac salt, as recited in claim 1. At the time the present application was filed, one of ordinary skill in the art would have considered shellac unsuitable for use as an enteric coating.

The Nivaggioli and Vasington references teach that alginate can be used in formulations that coat food items and pharmaceuticals. However, one of ordinary skill in the art, at the time the application was filed, would not have found it obvious to add shellac to an alginate based coating formulation for all the reasons stated above. Thus, even if the references are combined, it is respectfully submitted that the subject matter of claim 1 would not have been obvious in view of the references, and in view of the common knowledge that shellac is not suitable as an enteric coating.

The Applicant surprisingly discovered that although shellac alone is not suitable as an enteric coating, if a shellac salt is mixed with alginate, the resulting coating behaves well as an enteric coating. Specifically, the coating is able to withstand the acidic conditions present in a

patient's stomach, but it is broken down in the slightly alkaline conditions of the GI tract. Thus, an enteric coating that includes shellac and alginate selectively releases the contents of a dosage unit in the GI tract.

Because a coating formulation as recited in claim 1 would not have been obvious in view of the applied references, it is respectfully submitted that claim 1 is allowable. Claims 2, 5 and 8-15 depend from claim 1 and are allowable for the same reasons, and for the additional features which they recite. Withdrawal of the rejection on these grounds alone is respectfully requested.

Moreover, it is further respectfully submitted that the combination of Nivaggioli with Cook is improper.

One of ordinary skill in the art looking to improve the coating materials disclosed by Cook would have had no reason to incorporate the alginate disclosed in Nivaggioli. One of ordinary skill in the art would expect that the known qualities of shellac, the production of a shiny, smooth and attractive surface coating, and the qualities associated with alginate, improved mouth feel, would each be diminished by combining these two components. In other words, the addition of alginate would lead to a less shiny, smooth and attractive surface coating.

Moreover, the Cooke reference teaches that a shellac coating is formed by first forming an acidic solution containing shellac. The shellac is then precipitated out of the acidic solution on to a surface. However, one of ordinary skill in the art would know that alginate is insoluble in acidic solutions. As support for this fact, Applicant encloses a page from the 6<sup>th</sup> Edition of the *Handbook of Pharmaceutical Excipients* discussing the properties of sodium alginate. As shown therein, sodium alginate is essentially insoluble in acidic solutions.

Because sodium alginate is insoluble in acidic solutions, one of ordinary skill in the art would not have believed that it would have been possible to add sodium alginate to the acidic

shellac solutions disclosed by Cook. At the very least, one of ordinary skill in the art would expect to obtain very bad coating results from a mixture of sodium alginate and an acidic shellac solution.

Because one of ordinary skill in the art would not have believed it possible to add alginate to the acidic shellac solutions disclosed in Cook, it is respectfully submitted that the only way to find a motivation for adding alginate into the shellac solution comes from the impermissible use of hindsight, in view of Applicant's own invention.

For all the above reasons, it is respectfully submitted that the combination of Cook and Nivaggioli is improper. Withdrawal of the rejection of claims 1, 2, 5 and 8-15 on these additional grounds is respectfully requested.

### **III. CONCLUSION**

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

The Commissioner is authorized to charge the undersigned's deposit account #14-1140 in whatever amount is necessary for entry of these papers and the continued pendency of the captioned application.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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Attachments:

Excerpt from the *Handbook of Pharmaceutical Excipients*, 3<sup>rd</sup> Edition  
Excerpt from the *Handbook of Pharmaceutical Excipients*, 6<sup>th</sup> Edition